CDRH Final Guidance 2-Page Cover Sheet

Guidance for Industry

Retinoscope Guidance

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U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Diagnostic and Surgical Devices Branch
Division of Ophthalmic Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Division of Ophthalmic Devices, HFZ-460, 9200 Corporate Blvd, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Everette T. Beers, Ph.D. at 301/594-2018.

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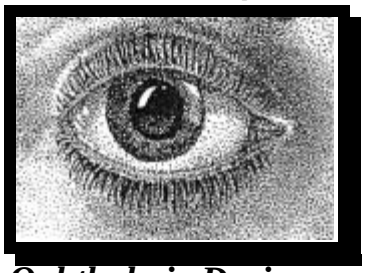
Division of



Ophthalmic Devices

Retinoscope Guidance[1]

Version 1.0

I. Device Description

Common Name:	Retinoscope
Class:	II
Classification Panel:	86
Product Code:	HKL (AC) and HKM (DC)
Regulation Number:	886.1780
Description:	A retinoscope is an AC-powered or battery-powered device intended to measure the refraction of the eye by illuminating the retina and noting the direction of movement of the light on the retinal surface and of the refraction by the eye of the emergent rays.
Inclusions/Exclusions:	This guidance excludes DC-powered retinoscopes (HKM) which are Class I Exempt

II. Indication for Use

A retinoscope is intended to measure the refraction of the eye by illuminating the retina and noting the direction of movement of the light on the retinal surface and of the refraction by the eye of the emergent rays.

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[1] This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statue, regulations, or both.

III. Required 510(k) Information

Device Trade or Proprietary Name
Device Common or Usual Name
Establishment Registration Number (if establishment registered)
Class
Classification Panel
Action taken to comply with Section 514 of the Act
Proposed labels, labeling, and Advertisements (if available) which describe the device, its intended use, and directions for use
Truthful and Accurate Statement
510(k) Statement or Summary
Indications for Use Form
The Marketed Device(s) to which equivalence is claimed including labeling and description of the device(s) and 510(k) number(s), if known.
Statement, table or chart of similarities and differences with Marketed Device(s)

IV. Additional Information Required Under 21 CFR 807.87(h)

Submitter's Name and Address
Contact Person, Telephone and Fax Number
Table of Contents with Pagination
Address of Manufacturing Facility/Facilities, and Sterilization Facility (if appropriate)

V. Information Specific for this Device

A. Materials: No flammable materials may be near the light source.

B. General Equivalency: For purposes of the 510(k) notification, provide a side-by-side comparison of the device with the predicate, noting similarities and explaining any differences, for the following items:

1. intended uses;

2. method of operation;

3. exposure parameters;

4. data collection and/or display systems;

5. flammability of materials;

6. maximum temperature of parts of the device held by the operator or accessible to the patient; and,

7. brightness controls.

C. Optical Equivalency and Radiation Safety: *Retinoscopes using Class 1 lasers are exempt from this requirement.* In addition to the above, establish equivalent effectiveness and optical radiation safety of the device by complying with either 1., 2., or 3. below:

1. Certify compliance with section 4.4 “Optical radiation hazard with retinoscopes” (along with section 5.2 and Annex C) of the ISO (International Standards Organization) 12865.

2. Demonstrate that the optical radiation emissions from the device do not exceed the Threshold Limit Values (TLVs) for optical radiation established by the American Conference of Governmental Industrial Hygienists (ACGIH) under worst case clinical exposure conditions and times for all intended uses and applications. This analysis must include a comparison of the optical radiation emissions from the device to the TLVs for Ultraviolet and infrared radiation, and visible and near infrared radiation (i.e., blue light and aphakic hazards). NOTE: Worst case clinical exposure conditions and times refers to the exposure of a patient's eye to the maximum intensity of light emitted from the device for the longest expected exposure times for each intended use and application. Or,

3. Provide a side-by-side comparison using either a. or b. below:

   a. Compare the critical elements of the device (e.g., light source, lenses, filters, other optical elements in the optical path) to those of a predicate or another legally marketed device. Include a side by side comparison of:

      (1) beam geometry (solid angle subtended by the initial condensing lens at the source, significant light losses in the optical path, and retinal area illuminated);

      (2) the light source and its operating characteristics (electrical power and effective color temperature); and

      (3) the optical characteristics of all components including spectral transmittance and the reflective/transmissive properties of any lenses, glass diffusion windows or filters. Also include the names and model identifications of the manufacturers of the critical components.

   b. Compare the optical radiation emissions associated with the device to those of a predicate or another legally marketed device. The comparison should include (1), (2) and either (3) or (4) below:

(1) the relative spectral radiant power distribution or any other relative spectral radiometric distribution over the wavelength range from 400 nm to 700 nm;

(2) the maximum photometric luminance; and either

(3) the maximum radiometric quantities:
(i) spectral irradiance or spectral radiance over the ultraviolet (UV) wavelength range from 250 nm to 400 nm, and,
(ii) irradiance for infrared (IR) wavelengths greater than 700 nm; or

(4) the optical radiation hazards as defined by ISO 15004 for:
(i) ultraviolet and infrared radiation, and
(ii) visible light and near IR radiation (blue-light weighted radiance and aphakic weighted radiance).

D. Electrical Safety: Demonstrate electrical safety with bench testing, or declare conformance to an electrical safety standard recognized by FDA (e.g., International Electrotechnical Committee (IEC) 60601-1), or certify compliance with other electrical safety standards (e.g., Underwriters Laboratory (UL) 544, UL 2601-1, etc.; testing data may be required). See Appendix II, "Declaration of Conformity to a Recognized Standard".

E. Software (if applicable): Device should comply with "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review (August 29, 1991)" and "ODE Guidance for the Content of Premarket Submission Containing Software - Draft Document", which will replace the 1991 guidance when finalized. Or, you may declare conformance to IEC 60601-1-4 (See Appendix II, "Declaration of Conformity to a Recognized Standard").

F. Sterilization: Not required.

G. Disinfection: Parts of the device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use, disposable cover.

H. Labeling: Include draft advertising, package labeling and user's manual with instructions for use. Labeling should comply with the following:

1. General labeling requirements:

a. Labeling should include Device manufacturer name and address (21 CFR 801.1).

b. Labeling should comply with all other applicable sections of 21 CFR 801 and section 502 ("Misbranded drugs and devices") of the Federal Food, Drug, and Cosmetic Act.

2. Device specific labeling requirements:

   a. Labeling should include the Prescription device caution: ("Caution: Federal law restricts this device to sale by or on the order of a Physician or Practitioner") (CFR 801.109(b)(1)).

   b. Labeling should include cleaning and disinfection procedures.

   c. Phototoxicity: The following information should be provided to the user:

      "Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (< 400 nm) and, whenever possible, filters that eliminate short-wavelength blue light (<420 nm).

      "The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

      "While no acute optical radiation hazards have been identified for retinoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography."

   d. Lasers: Products using lasers must comply with 21 CFR sections 1040.10 and 1040.11 and must be labeled according to 21 CFR 1040.10 (g).

VI. References

IEC 60601- 1 - Medical electrical equipment - Part 1: General requirements for safety
IEC 60601- 1- 4 - Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral Standard: Programmable electrical medical systems.

ISO 12865 - Ophthalmic instruments - Retinoscopes
ISO 15004 - Ophthalmic instruments - General requirements and test methods
*In the United States, copies of these standards can be obtained from the American National Standards Institute (ANSI), 11 West 42nd Street, New York, NY 10036.

UL 544 - Professional Medical and Dental Equipment
UL 2601-1 - Medical electrical equipment - Part 1: General requirements for safety

Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review (August 29, 1991)
ODE Guidance for the Content of Premarket Submission Containing Software - Draft Document (available at www.fda.gov/cdrh/ode/dtswguid.html)

1998 TLVs and BEIs: Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, American Conference of Governmental Industrial Hygienists, (ACGIH, Cincinnati, OH), 1998.

ANSI/IESNA RP 27.1-96: Recommended Practice for Photobiological Safety for Lamps & Lamp Systems - General Requirements.

ANSI/IESNA RP 27.3-96: Recommended Practice for Photobiological Safety for Lamps - Risk Group Classification & Labeling.

APPENDIX I

Checklist for Retinoscopes

Information for the following items should be provided in a 510(k) submission:

General Requirements:

- Submitter's Name and Address
- Contact Person, Telephone and Fax Number
- Table of Contents with Pagination
- Address of Manufacturing Facility/Facilities, and Sterilization Facility (if appropriate)

- Device Trade or Proprietary Name
- Device Common or Usual Name
- Establishment Registration Number (if establishment registered)
- Class
- Classification Panel
- Action taken to comply with Section 514 of the Act
- Proposed labels, labeling, and Advertisements (if available) which describe the device, its intended use, and directions for use
- Truthful and Accurate Statement
- 510(k) Statement or Summary
- Indications for Use Form
- The Marketed Device(s) to which equivalence is claimed including labeling and description of the device(s) and 510(k) number(s), if known.

Device Specific Requirements:

- Materials (no flammable materials near light source)
- Side-by-side comparison with predicate(s) (statement, table or chart of similarities and differences with Marketed Device(s)
- Optical equivalency and radiation safety certification or measurements
- Electrical safety
- Software certification
- Disinfection information
- Labeling: prescription device caution; disinfection procedures; phototoxicity information; laser product labeling

APPENDIX II

Declaration of Conformity to a Recognized Standard

In preparing a declaration of conformity to recognized standards, manufacturers should refer to the guidance document entitled, "Guidance on the Recognition and Use of Consensus Standards." In accordance with this guidance, declarations of conformity to recognized standards should include the following:

- An identification of the applicable recognized consensus standards that were met;
- A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below;
- An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed;
- An identification, for each consensus standard, of any requirements that were not applicable to the device;
- A specification of any deviations from each applicable standard that were applied (e.g., deviation from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70));
- A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference; and,
- The name and address of any test laboratory or certification body involved in determining the conformance of the device with the applicable consensus standards and a reference to any accreditations of those organizations.